REMARKS/ARGUMENTS

The Amendments

Claims 1, 4, 9-14, 16-34, and 40-49 were in the application. Claims 45-49 stood withdrawn, and have now been cancelled without prejudice to the prosecution of their subject matter in related divisional, continuation, and continuation-in-part applications.

In addition, claims 1-16, 18-20, 25, 35-39, and 50-59 also stand cancelled, without acquiescence to any rejections and without prejudice to the prosecution of their subject matter in related divisional, continuation, and continuation-in-part applications.

Claims 17 and 21 have been amended to recite the subject matter of cancelled claim 1, from which they originally depended. Further amendments have been made to accommodate claim dependency necessitated by the cancellation of claim 1.

New claims 60-68 recite the subject matter of claims 26-34 (which now depend from claim 17, instead of from cancelled claim 1) with the difference being in their depending from claim 21 (instead of from cancelled claim 1).

No new matter is added by way of the claim amendments or by way of the new claims.

Rejection under 35 U.S.C. § 112, first paragraph. (Enablement)

Claims 1, 4, 9-14, 16-34 and 40-44 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly not being enabled. Claims 1-16, 18-20, and 25, 35-39 stand cancelled, so the rejections to claims 1, 4, 9-14, and 18-20, and 25 are believed to be moot.

Applicants acknowledge the USPTO's statement that the specification is enabling for (1) an isolated fusion molecule comprising a human IgG heavy chain constant region consisting of either the amino acid sequence SEQ ID NO: 2 or the amino acid sequence of SEQ ID NO: 3, capable of binding to a native IgG inhibitory receptor directly fused to a myelin basic protein or an epitope of myelin basic protein consisting of the amino acid sequence of SEQ ID NO:13 (see, e.g., page 2, point 7; page 13, lines 5-13; and elsewhere in the Office Action).

Applicants note that pending claims 17 and 21 are directed to isolated fusion molecules comprising a human IgG heavy chain constant region consisting of either the amino acid sequence SEQ ID NO: 2 or the amino acid sequence of SEQ ID NO: 3, and are capable of binding to a native IgG inhibitory receptor directly fused to a myelin basic protein or an epitope of myelin basic protein. In addition, the specification including the amino acid sequence of SEQ ID NO: 13, Applicants submit that those of ordinary skill in the art are capable of preparing amino acid sequences having at least 90% sequence identity to the amino acid sequence of SEQ ID NO:13 without undue experimentation. The practice of the claims dependent from claims 17 and 21 are similarly within the capability those of ordinary skill in the art without undue experimentation.

For example, as discussed in previous Amendments, the Specification provides sufficient guidance to make a variety of advantageous fusion molecules comprising first and second polypeptide sequences. Applicant submits that fusion molecules comprising first and second polypeptides are fully enabled in view of 1) guidance provided throughout the Specification (in the Example and in other portions of the specification), 2) the routine nature of recombinant DNA engineering and the production of chimeric or variant polypeptides, as known in the art, and 3) the high level of technical competence of one of ordinary skill in the immunological, genetics and protein-chemistry arts. The routine nature of manipulation of DNA and protein molecules is well known, as evidenced by the publications cited in the Specification *(see,* especially, page 20, line 29 to page 21, line 24; page 64, lines 17 - 26). Detailed protocols for the construction of the fusion molecule variants described in the Specification is not necessary for one of ordinary skill to practice the claimed invention without undue experimentation. For the reasons set forth above, withdrawal of this portion of the rejection is requested.

Accordingly, in view of the acknowledgment of enablement by the USPTO, and in view of these remarks and of previous remarks in prior Amendments, Applicants submit that the present claims are fully enabled under 35 U.S.C. § 112, first paragraph and respectfully request that the USPTO withdraw this rejection.

The Rejections under 35 U.S.C. § 112, first paragraph. (Written Description)

Claims 1, 4-6, 9-14, 16--34 and 40-44 stand rejected under 35 U.S.C. § 112, first paragraph for allegedly lacking written description. Specifically, the USPTO alleges that there is insufficient written description in the Specification for the same fusion molecules that were rejected on the basis of lack of enablement (Office Action, pages 12-19). In particular, the USPTO is concerned with "the recitation of an isolated fusion molecule comprising a first polypeptide sequence comprising at least 85 % identity with a native human IgG heavy chain constant region ..." (page 12, point 8).

However, the present claims are directed to isolated fusion molecules comprising polypeptide sequences comprising an amino acid sequence having at least 98% identity to the amino acid sequence of SEQ ID NO: 3, directly functionally connected to a second polypeptide autoantigen sequence comprising at least 90% sequence identity to a portion of the amino acid sequence of myelin basic protein (MBP) (claim 21; claim 17 recites even greater sequence identity). As amended, the present claims do not include any recitation of a sequence "comprising at least 85 % identity with a native human IgG heavy chain constant region ..." and the rejections are thus believed to be moot. In addition, the specification provides a disclosure of the CH2-CH3 regions of human IgG heavy chain constant region.

Accordingly, the specification describes the claimed invention in sufficient detail that one of ordinary skill in the art can reasonably conclude that the inventor had possession of the claimed invention (e.g., *Vas-Cath, Inc. v. Mahurkar,* 935 F.2d at 563, 19 USPQ 2d at 1116 and *Gentry Gallery, Inc. v. Berkline Corp.,* 134 F.3d 1473, 45 USPQ 2d 1498 [Fed. Cir. 1998]). The Specification provides adequate written description for fusion molecules of claim 1, especially in view of the state of the prior art, and the high level of skill in the art.

For the above reasons, Applicant asserts that there is sufficient written description of the claimed invention under 35 U.S.C. § 112, first paragraph and respectfully requests that the Examiner withdraw this rejection.

The Rejections under 35 U.S.C. § 102(b)

Claims 1, 4, 9-14, 19, 24, and 40-41 stand rejected as allegedly anticipated by WO 00/01732.

However, as claims 1, 4, 9-14, and 19 stand cancelled in the present amendment, the rejections of these claims is believed to be moot.

Applicants acknowledge the statement that claims 17 and 21 are free of prior art (page 28, point 18 of the present Office Action). Applicants further note that claims 24 and 40-41 now depend from claims 17 and 21. Accordingly, being directed to subject matter that is dependent from claims that are free of prior art, and further limiting these claims, Applicants submit that claims 24 and 40-41 are also free of prior art and that the rejections of these claims as allegedly anticipated by WO 00/01732 is overcome.

The Rejections under 35 U.S.C. § 103(a)

Claim 10 stands rejected under 35 U.S.C. § 103(a) as allegedly obvious over WO 00/01732 in view of US 5,858,980. However, as claim 10 stands cancelled in the present Amendment, this rejection is believed to be moot.

Claims 1, 16, and 22-28 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over WO 00/01732 in view of US 5,116,964. However, as claims 1, 16 and 25 stand cancelled in the present Amendment, the rejections of claims 1, 16 and 25 are believed to be moot.

Claims 22-24 and 26-28 depend from claims 21 and 17. As acknowledged by the USPTO, claims 17 and 21 are free of prior art. In addition, there is no suggestion in the prior art of the amino acid sequences required by claims 17 and 21, and no motivation to provide those sequences. Accordingly, claims 22-24 and 26-28 being dependent from the novel and surprising claims 17 and 21, and including elements that are not provided or suggested in any combination of the prior art, Applicants submit that claims 22-24 and 26-28 are not obvious over WO 00/01732 in view of US 5,116,964, and submit that the rejections of 22-24 and 26-28 under U.S.C. § 103(a) as allegedly obvious over WO 00/01732 in view of US 5,116,964 are overcome.

Claims 1 and 17-20 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over WO 00/01732 in view of US 5,565,335. However, as claims 1 and 18-20 stand cancelled in the present Amendment, the rejections of claims 1 and 18-20 are believed to be moot.

Claim 17 is acknowledged to be free of prior art. Thus, claim 17 is directed to novel subject matter, and includes elements not disclosed or provided by any combination of the prior art. Moreover, the prior art fails to suggest elements of the claimed invention, including failing to suggest the amino acid sequence of SEQ ID NO: 2. In addition, the combined references also fail to provide motivation to provide the amino acid sequence of SEQ ID NO: 2.

Thus, requiring, among other elements, an IgG heavy chain constant region sequence having the sequence of SEQ ID NO: 2, and SEQ ID NO: 2 not being suggested or provided in the prior art, Applicants submit that the subject matter of claim 17 is not made obvious by the cited references. Accordingly, Applicants submit that the rejection of claim 17 under 35 U.S.C. § 103(a) is overcome.

Claims 29-34 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over WO 00/01732 in view of US 5,116,964 and further in view of Elias and of Marks. However, as claims 29-34 stand amended to depend from claim 17, and as claim 17 is free of prior art, claims 29-34 include elements that are not disclosed in any combination of prior art.

In addition, claims 29-34 include elements that are not suggested in any combination of prior art, and include elements for which the prior art supplies no motivation to provide in an alleged attempt to make the claimed invention. Claim 17 including, for example, among other elements, an IgG heavy chain constant region sequence having the sequence of SEQ ID NO: 2, and SEQ ID NO: 2 not being suggested or provided in the prior art, Applicants submit that the subject matter of claims 29-34 is not made obvious by the cited references. Accordingly, Applicants submit that the rejections of claims 29-34 under 35 U.S.C. § 103(a) are overcome.

Claims 42-44 stand rejected under 35 U.S.C. § 103(a) as allegedly obvious over WO 00/01732 in view of US 5,945,294. However, as claims 42-44 stand amended to depend from claims 17 and 21, and as claims 17 and 21 are free of prior art, claims 42-44 include elements that are not disclosed in any combination of prior art, and are directed to non-obvious subject matter.

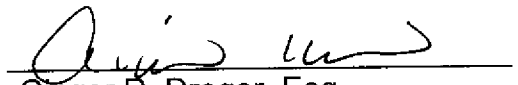
Claims 42-44 being directed to articles of manufacture that comprise the novel, and not obvious, compositions of claims 17 and 21, and the cited prior art failing to disclose or to suggest, or to motivate one of ordinary skill in the art to provide, the novel compositions of claims 17 and 21 that are required for claims 42-44, Applicants submit that claims 42-44 are not made obvious by the combination of the cited references. Accordingly, Applicants submit that the rejections of claims 42-44 under 35 U.S.C. § 103(a) are overcome.

Conclusion

Applicant submits that the present claims are in condition for allowance, and respectfully request issuance of a notice of allowance. If the Examiner believes that any matters remain outstanding, however, Applicant respectfully invites the Examiner to call the undersigned to schedule a telephonic interview.

Respectfully submitted,

Date: January 3, 2008



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